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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,570	09/15/2003	Jonathan S. Stinson	81636D	9734
23685 7590 09/12/2007 KRIEGSMAN & KRIEGSMAN 30 TURNPIKE ROAD, SUITE 9 SOUTHBOROUGH, MA 01772			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,570

Applicant(s)

STINSON ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-49 is/are pending in the application.
- 4a) Of the above claim(s) 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-34 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Regarding the information disclosure statement filed 09/15/03, examiner has been unable to acquire a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Examiner respectfully requests that applicant submit copies of these documents for consideration in the next office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "larger than a diameter of an enodiliary tube" in claim 48 is a relative limitation, which renders the claim indefinite. Since the claim is relying on a size of a body part, which will vary from person to person, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

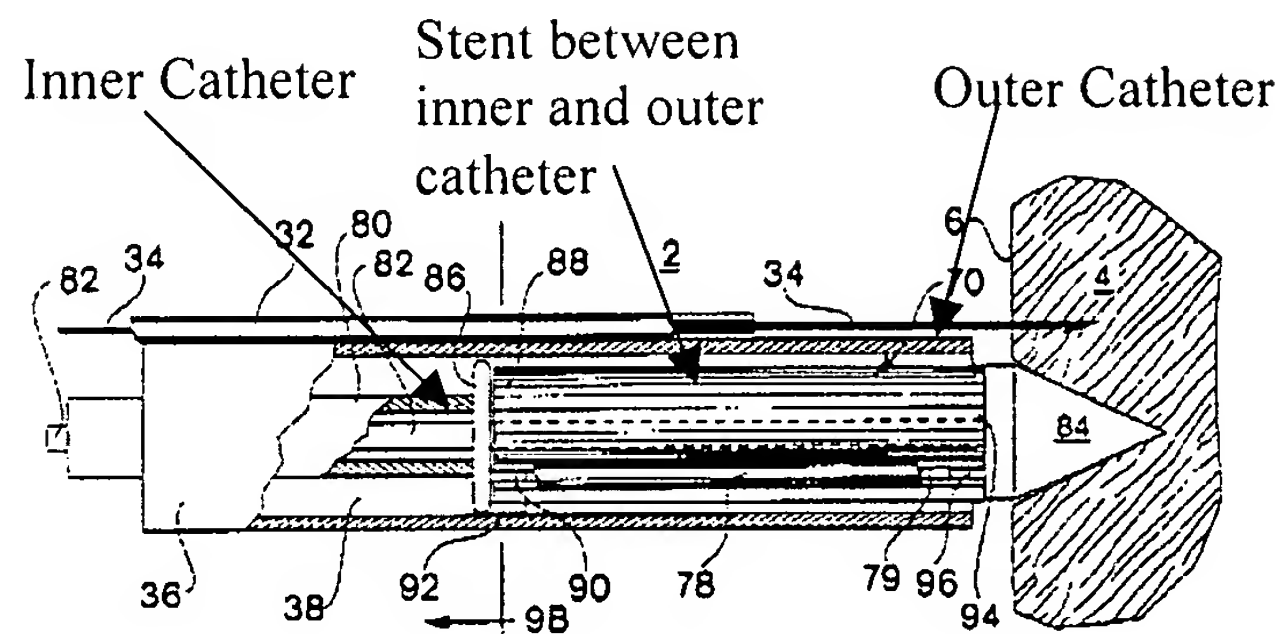
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 24, 26-28, 30, 31 and 33 rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al (USPN 6,458,092).**

5. Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter (see below). The stent can be a braided filament (Fig. 5a, b) or non-absorbable plastic (Col 12, line 64). The stent has uniform diameter (Fig. 1B) and is shaped to include a waist of lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 1D). The perforating means is a retractable needle.



6. **Claims 24, 25, 29-31, 33, 47 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Phelps et al (USPN 6,290,728).**

7. Phelps discloses a stent delivery system comprising: an inner catheter (22) with a first lumen; perforating means (16) slidably disposed in the first lumen; an outer catheter (26) **adapted** or capable of axial movement relative to the inner catheter (C 6: L23 states that the outer sheath is **withdrawn**, implying that it would be capable of being pulled back based on the definition of withdrawn (see remarks)); a self expandable stent (20) disposed between the inner and outer catheter. The stent is coaxially mounted over the inner catheter. The stent is made of bio-absorbable material (Col 7, line 33). One embodiment of a stent has uniform diameter (Fig. 12) and another is shaped to include a waist of lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 4). The perforating means is a retractable needle. The stent is adapted to or capable of draining a gastric pseudocyst and the stent will have a diameter larger than a diameter of an endobiliary tube (C 9:L21 Phelps contemplates using the stents as biliary stents).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 24, 25, 27, 30, 33, 34, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (USPN 6,599,315) in view of Haarstad et al (USPN 6,533,753).**

10. Wilson discloses a stent delivery system comprising: an inner catheter (120) with a first lumen (125) with a guide wire (150) slidable disposed in the first lumen; a second lumen (126) with a guidewire (151) slidably disposed in the second lumen; and a self expandable stent (20) (Col 6, line 62) coaxially disposed over the inner catheter and an outer catheter (guiding catheter (C8: L58) that is adapted to move axially relative to the inner catheter. The stent is made of non-absorbable material (Col 6, lines 38-42). The stent has uniform diameter. The stent is adapted to or capable of draining a gastric pseudocyst. The stent will have a diameter larger than a diameter of an endobiliary tube when the endobiliary tube is in an infant.

11. Wilson does not disclose that the first guidewire is a perforating means that is a retractable needle.

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12. Haarstad discloses that it is well known in the art to use a stiff guidewire to penetrate lesions referred to as "chronic total occlusions" (Col 1, lines 40-51). In this case the guidewire is considered the perforating means or needle.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a stiff guidewire into the stent delivery device in order to more easily traverse a stenosis that may be fully occluding the vessel. It is well known in the art as evidenced by Haarstad.

14. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (USPN 6,599,315) in view of Haarstad et al (USPN 6,533,753) as applied to claim 47/1 above and further in view of Patterson (USPN 6,165,209).

15. Wilson in view of Haarstad discloses the invention substantially as claimed as stated above except for the dimensions of the diameter of the stent. Wilson discloses that the stent is used for repairing an artery having septal perforations.

16. Patterson discloses that it is typical for stents that are used in arteries to have an diameter from 4 to 10 mm (C6: L 50-55).

17. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a diameter of about 8mm into the stent disclosed by Wilson since it is well known in the art to modify the size of the stent depending on the location of the body in which it is placed. Patterson discloses that it is well known to use a stent with the claimed diameter. It is further obvious to one of skill in the art to change the size of stents based on the size of the patient. Such a modification would have involved

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a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

18. **Claims 32 and 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps in view of Anderson (USPN 6,290,728).**

19. Phelps discloses the invention substantially as claimed except for the exact dimensions. Phelps also discloses that in addition to being used in the myocardium, the stent system can be used for biliary or esophageal stents (C 9:L21).

20. Anderson discloses a biliary stent and stents used for shunts that fall within the claimed parameters (C7:L 16-30).

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to change the size of the stent since the claimed dimensions are well known in the art for use in biliary stents. It is further obvious to one of skill in the art to change the size of stents based on the size of the patient. Such a modification would have involved a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

22. **Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale.**

23. Phelps, Gambale and Wilson in view of Haarstad, disclose the invention substantially as claimed as stated above except for the disclosed dimensions of the

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diameter and the length of the stent. It would have been obvious to change the size of the stents based on the size of the person or animal in which the stent is being placed. For instance, when using the apparatus in an infant, one would require a much smaller size than in an adult. In the same respect when using the apparatus on a large animal, for example an elephant, one would require a much larger size than that used on a human. Additionally, such a modification would have involved a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

24. Applicant's arguments filed 06/06/07 have been fully considered but they are not persuasive.

25. Regarding the Gambale reference, applicant states that the prior art does not disclose a stent positioned between the inner and outer catheter. As shown in the figure above, Gambale does disclose a stent that is between the two catheters along the longitudinal axis.

26. Regarding the Phelps reference and the limitation of an outer catheter "adapted for axial movement relative to the inner catheter", Phelps discloses that the "retaining sheath (26) is withdrawn" (Col6: L23). The following are two definitions of the term withdrawn:

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a. To take back or away; remove. (Dictionary.com. *The American Heritage®*

Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004.

<http://dictionary.reference.com/browse/withdraw> (accessed: August 30, 2007).)

b. pull back or move away or backward (Dictionary.com. *WordNet® 3.0*.

Princeton University. <http://dictionary.reference.com/browse/withdraw> (accessed:

August 30, 2007).

The outer catheter, which is withdrawn, is pulled backward and therefore it is inherent that the inner catheter moves axially relative to the inner catheter.

27. Secondly, the claim states “**adapted** for axial movement” merely requiring that the device be **capable** of axial movement. Examiner asserts that the terminology “withdrawn” provides ample support for the limitation that requires that the outer catheter be capable of axial movement.

28. Applicant argues that there is no mechanism described for the action of “withdrawing” to equate the action to axial movement. Examiner is unsure of what mechanisms of withdrawing would not necessitate axial movement of the sheath to pull it proximally and remove it from the location of the stent. The only other option would be a rip seam that opens the sheath to allow the stent to expand, leaving the sheath in place surrounding the stent. Examiner does not believe this to be normal practice.

However if this is what the examiner is intending, the following is applicable. Phelps discloses that after the stent is delivered, that the inner catheter is removed (C6: L31) which would necessitate that the inner catheter is withdrawn axially through the stent lumen. At this point, the outer sheath would be capable of axial movement *relative* to

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the inner catheter. Regardless of what component is being moved the two components are movable relative to each other.

29. Finally, additional support for the sheath moving axially is found in the embodiment of Figs. 14-26. C 8: L19 states that the delivery catheter is "retracted proximally". This indicates that Phelps contemplated the idea of axial movement of the outer sheath and that it is by no means a novel concept.

30. Regarding the Phelps reference with regard to claim 47, applicant states that there would be no reason to reconfigure the cardiac stent to permit drainage of a pseudocyst. Examiner is not relying on reconfiguring the stent, since the claim merely requires that the stent be "**adapted to**" or **capable** of draining a gastric pseudocyst. Regarding the change in dimensions, examiner reiterates that the change would be necessitated by the size of the patient.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER
9/4/07.